REMARKS

Consideration and entry of this paper, and reconsideration and withdrawal of any and all objections to and rejections of the application, and allowance of the claims, especially in view of the amendments and remarks made herein, are respectfully requested, as this paper places the application in condition for allowance, or in better condition for appeal.

I. Status of the Claims and Formal Matters

Claims 52-81 are pending in this application. By this paper, claims 52-54, 56-58, 64-65, and 67-69 are amended and claim 66 is cancelled. Support for these amendments is found in the specification. These amendments have been made simply for clarification and to place the claims in condition for allowance, or in better condition for appeal. No new matter has been added by these amendments.

By this paper new claims 70-81 have been added. These claims have been added for clarification and to place the claims in condition for allowance, or in better condition for appeal. In addition, these new claims round out the scope of the protection to which the Applicant is entitled. No new matter has been added by the addition of these new claims. Support for the new claims is found throughout the specification. Specifically, support for the negative control nucleic acids of claims 70-81 and the positive control nucleic acids of claims 76-81, is found in Example 1 of the present application at pages 16-21. Example 1 illustrates 50 different *Staphylococcus aureus* strains that give a positive result in both PCR and hybridization using the primers and/or probes of the present invention (i.e. suitable positive controls), and 124 different non-*Staphylococcus aureus* bacterial species that give a negative result in both PCR and hybridization using the primers and/or probes of the present invention (i.e. suitable negative controls).

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the documents cited by the Examiner, and that these claims were in full compliance with the requirements of 35 U.S.C. §112. The amendments of and additions to the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

II. Sequence Rules

The Final Office Action states that the amendment filed on 7/2/02 requesting cancellation of SEQ ID NO: 13, 14, 15, and 19 is not proper. In accordance with the sequence rules, a replacement sequence listing and CRF canceling SEQ ID NO: 13, 14, 15, and 19, is submitted herewith. Consequently, it is believed that entry of this amended Sequence Listing raises no issues of new matter and that entry of the Sequence Listing is proper.

The Statements required by 37 C.F.R §1.821(f) and (g) are set forth below.

Pursuant to 37 C.F.R. §1.821 (g), the undersigned hereby states that this submission, filed in accordance with 37 C.F.R. §1.821 (g), does not contain new matter.

Pursuant to 37 C.F.R. §1.821 (f), the undersigned hereby states that the content of the paper and computer readable copies of the Sequence Listing submitted in accordance with 37 C.F.R. §1.821 (c) and (e), respectively, are the same.

III. Specification

The Final Office Action alleges that Figures 1-10 and SEQ ID NO: 6-12 and 14-18 constitute new matter because they each recite sequences that were not supported by the specification of the international application as originally filed. The Examiner requests cancellation of what she believes to be new matter. Applicants are currently investigating this situation, and a Supplemental Amendment to address this issue will be filed in due course.

IV. The Rejections Under 35 U.S.C. § 112 (second paragraph) are overcome

The Final Office Action alleges that claims 53-66 are indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. Specifically, the Final Office Action alleges that it is not clear whether claims 53 and 54, and claims 55 –57 which depend from claim 54, are directed to a kit comprising a probe comprising a nucleic acid that differs from SEQ ID NO: 1 by at least one nucleotide, or a kit comprising a probe that could identify and discriminate between SEQ ID NO: 1 and a sequence that differs from SEQ ID NO: 1. In addition, the Final Office Action alleges that the phrase "said nucleic acid molecule and/or probe" in claim 55 lacks proper antecedent basis, and that claims 59-66 are indefinite as they depend from claim 52, which also recites more than one probe. It is also alleged that it is not clear how claims 56, 57, and 58 further limit the claims from which they depend, and that it is not clear what is meant by the recitation "analogous nucleotides" in claims 64-66.

These rejections are respectfully traversed.

By this paper, claims 52-54, 56-58, 64-65, and 67-69 have been amended to more clearly recite the subject matter of the invention, and claim 66 has been cancelled, rendering the rejections moot. Thus, reconsideration and withdrawal of the rejections to the application under 35 U.S.C. § 112 (second paragraph), is respectfully requested.

V. The Rejections Under 35 U.S.C. § 112 (first paragraph) are overcome

The Final Office Action alleges that claims 52-54, 58, 59 and 60-66 of the present application contain subject matter which is not described in the specification in such as a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention at the time the application was filed. The Examiner states that "the genus encompassed within the instant claims is quite large, encompassing nucleic acids that have fragments of SEQ ID NO: 1 embedded in any framework". The Office Action further alleges that the inventors could not be in possession of *all* the possible combinations of probes and/or primers that span the 171 base pair region of SEQ ID NO. 1.

This rejection is respectfully traversed.

The assertion that the genus of primers and/or probes that span the 171 base pairs of SEQ ID NO. 1 is too large is not reasonable. The genome of *S. aureus* comprises around 8 million base pairs and approximately 2600 open reading frames. The present invention identifies a 171 base pair region with this genome that is sufficiently conserved between all strains of *Staphylococcus aureus*, but sufficiently divergent from genomic sequences of other *Staphylococcus* species and other bacterial genera, to be useful for the accurate and specific detection of *Staphylococcus aureus* strains. As demonstrated in Example 1 of the present application, the claimed primers and probes were able to specifically amplify (or hybridize with) nucleic acid sequences of fifty different *Staphylococcus aureus* strains, while failing to non-specifically cross-react with nucleic acid sequences of 124 different non-*Staphylococcus aureus* bacterial species. Thus, the present invention teaches that primers and/or probes designed to bind to a region comprising only 0.002% of the genome of *Staphylococcus aureus* strains can be used for the specific detection of *S. aureus* strains. Compared to the genus of primers and probes that could be made to bind to the entire *Staphylococcus aureus* genome, the genus of the primers and probes taught by the present invention can hardly be considered to be unreasonably large. Choosing and designing specific probe and/or primer sequences that bind to the 171 base pair sequence of SEQ ID NO. 1, is well within the possession of the inventors, and is well within the

capabilities of anyone skilled in the art of molecular biology. Thus, the present invention need not provide sequences of all possible probes and/or primers that bind to this region. Rather, examples of a few suitable primers and probes, such as those described throughout the specification of the instant application, should be sufficient.

VI. The Rejections Under 35 U.S.C. § 102(b) are overcome

The present Office Action rejects claims 52-63 and 67-69 as allegedly being anticipated by Kunsch et al. (CA 2194411), which teaches the sequence of the *Staphylococcus aureus* genome and nucleic acid probes that hybridize to the RNA or DNA of *Staphylococcus* aureus.

This rejection is respectfully traversed.

Although Kunsch et al. teaches the sequence *Staphylococcus aureus* genome, it fails to provide any teaching about which regions within the 8 million base pair genomic sequence are sufficiently conserved between all strains of *Staphylococcus aureus*, but are sufficiently divergent from the sequences of other bacterial species, to be useful for the unequivocal detection of all *Staphylococcus aureus* strains. Thus, although the sequences Kunsch et al. could be used in the detection of the particular *Staphylococcus aureus* strain from which the sequence is derived, Kunsch et al. provides no teaching regarding which sequences within the 8 million base pair genome could be used to detect other *Staphylococcus aureus* strains, such as for example coagulase-negative *Staphylococcus aureus* strains. Similarly, Kunsch et al. provides no teaching regarding which sequences within the 8 million base pair genome would not cross-hybridize/cross-react with other non-*Staphylococcus aureus* bacterial species. As such, Kunsch et al. fails to teach a primers or probes that can be used for the specific detection of multiple *Staphylococcus aureus* strains (ncluding coagulase-negative *Staphylococcus aureus* strains), without cross-reactivity with other bacterial species, as is taught by the present invention. By this paper, claims 52-63 and 67-69 have been amended to more clearly recite how the primers and probes of the present invention uniquely allow the specific detection of multiple *S. aureus* strains without cross-reactivity with other bacterial species.

VII. The Rejections Under 35 U.S.C. § 103 are overcome

The Final Office Action alleges that claims 64-66 are obvious over Kunsch et al., in view of Buchardt et al.

This rejection is respectfully traversed.

Kunsch et al. discloses the sequence of the *S. aureus* genome. Buchardt et al. teaches that peptide nucleic acids (PNAs) can be substituted for DNA to generate DNA mimics for use as probes.

As described above, Kunsch et al. fails to teach which sequences within the 8 million base pair genome could be used to detect multiple *Staphylococcus aureus*, such as for example coagulase-negative *Staphylococcus aureus* strains, and also fails to teach which sequences within the 8 million base pair genome would not cross-hybridize/cross-react with other non-*Staphylococcus aureus* bacterial species. Thus, Kunsch et al. fails to teach a primers or probes that can be used for the specific detection of multiple *Staphylococcus aureus* strains (including coagulase-negative *Staphylococcus aureus* strains), without cross-reactivity with other bacterial species, as recited in the currently amended claims. Since claims 64-66 are not anticipated by Kunsch et al., they are not rendered obvious by the combination of Kunsch et al. and Buchardt et al. The primers and probes presently claimed are not obvious regardless of whether DNA or PNA is used in their construction.

CONCLUSION

In view of the amendments and remarks herewith, which are fully responsive to the rejections, the application is in condition for allowance or in better condition for appeal. Consideration and entry of this paper, favorable reconsideration of the application and reconsideration and withdrawal of the objections to and rejections of the application, and prompt issuance of a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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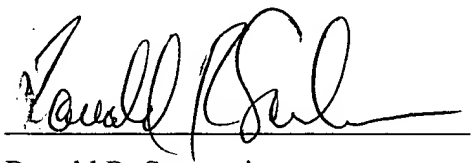
By: 

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